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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO.       |
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| 10/580,061   | 02/20/2007  | Peisheng Cao         | 14556.0007USWO                | 7583                   |
| 23552  | 7590        | 11/14/2007           |                               |                        |
| MERCHANT & GOULD PC<br>P.O. BOX 2903<br>MINNEAPOLIS, MN 55402-0903 |             |                      | EXAMINER<br>LEITH, PATRICIA A |                        |
|  |             |                      | ART UNIT<br>1655              | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>11/14/2007       | DELIVERY MODE<br>PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/580,061

Applicant(s)

CAO, PEISHENG

Examiner

Patricia Leith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 8-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9/15/06
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

Claims 1-19 are pending in the application.

### ***Election/Restrictions***

Applicant's election of Group I, claims 1-7 in the reply filed on 10/22/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 8-19 are hereby withdrawn from examination on the merits as these claims are directed toward a non-elected invention.

Claims 1-7 were examined on their merits.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-5 either recite, or depend upon a claim which recites 'raw material'. Further, claim 5 recites 'Chinese traditional medicine or plant.' It is deemed that Applicant has not set forth a representative number of examples in order to reasonably verify possession of such a potentially enormous number of materials or plants.

The MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claims 1-4 are broad generics, with respect to *all raw materials*. The possible variations of raw materials are limitless. Additionally, while claim 5 'narrows' 'raw materials' to 'Chinese traditional medicine or plant', this genus of plant materials/medicines is vastly broad. Applicant has disclosed *one* genus of plant; Angelica. This disclosure does not represent the enormous, *potentially millions* of types of 'raw materials' known on earth, or the thousands of Traditional Chinese medicines/plants known.

The MPEP states that the purpose of the written description requirement is to ensure that the invention had possession, as of the filing date of the application, of the specific subject matter later claimed by him or her. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F. 3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F. 2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, no that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F. 3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398. The specification lacks sufficient variety of species of 'raw materials' and medicines/plants to reflect this variance in the genus since the specification does not provide sufficient examples from such a genus.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F. 2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984)

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(affirming rejection because the specification does "little more than outline [goals] appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of 'raw material' as well as 'Chinese traditional medicine or plant' and does not reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed had possession of the entire scope of the claimed invention and thus, this rejection is proper.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites 'the raw material.' This phrase lacks antecedent basis in the claim thus leading to indefiniteness. Because claims 2-5 all depend upon claim 1 and do not correct the deficiencies of claim 1 under this statute, claims 2-5 are also rejected for being indefinite.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (US 4,018,755) in view of Bloom (US 5,902, 224). The rejection of claim 5 over Wang is evidenced by Soinneae, P. (1997)\*.

Wang (US 4,018,755) taught extraction of proteins from vegetable matter using sonication (nonlinear vibration) (see Abstract and Background, columns 1-2).

Wang discloses a specific example wherein 5 g of defatted soybean flakes obtained from cracking and dehulling (i.e., 'crushing') and solvent extraction were added to a jar with 50 ml (approximately 50 grams) of water, chilling the jar containing the defatted soybeans and water in an ice slurry and sonicating for 8 min., wherein the sonicator operated at a frequency of 20 KHz (nonlinear). The resulting mixture was centrifuged and the supernatant was recovered, yielding the soybean proteins (see Example 1, columns 2-3).

It is deemed that because the jar containing the water and the defatted soybeans was *chilled* in an ice slurry, that the temperature was within the Instantly claimed temperature range. It is deemed that the slurry would be about or colder than room temperature (18°C to 23 °C) but higher than freezing (0°C).

As evidenced by Soinneae, P., soybean was a Chinese Traditional plant, from which medicines were obtained (see p. 59).

Wang did not specifically teach wherein the extraction occurred for 1 to approximately 3 hours, wherein the extraction temperature was 20 °C to approximately 50°C, wherein the extraction was under the pressure of 25~35 Mpa (megapascals) or wherein the ration of raw material to water was 1:3~5.



Centrifuges which operated at the claimed Mpa range were known in the art. For example, Bloom (US 5,902, 224) taught a centrifuge which operated between 2,300 and 5,000 psi ( ~15.9 Mpa to ~ 35 Mpa).

Claim 1 states 'comprising' and does not require any particular order of method steps. Further, it is deemed that the centrifugation process as disclosed by Wang was part of the 'extraction' procedure, as this step separates the solid plant waste from the analyte supernatant. One of ordinary skill in the art would have been motivated to use a centrifuge such as the one disclosed by Bloom in order to centrifuge the extraction mixture of Wang because the centrifuge of Bloom was a conventional centrifuge known in the art at the time the Invention was made.

Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. While Wang did not specifically teach that the temperature of the extraction was 20 °C to approximately 50°C or wherein the ration of raw material to water was 1:3~5, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal temperature conditions as well as solid/extraction liquid ratio as these are considered art-recognized result-effective variables which would have been routinely determined and optimized. Further, if there are any differences between Applicant's claimed

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method and that suggested by the combined teaching of the prior art, the differences would be appear minor in nature. Although the prior art did not specifically teach that the temperature of the extraction was 20 °C to approximately 50°C, one of ordinary skill in the art would have recognize that the proteins of Wang could have been extracted at room temperature, or at least a temperature below the denaturation temperature of the protein. While the prior art does not teach that the ratio of raw material to water was 1:3~5, it is deemed that the adjustment of solid material to extraction solvent is merely a matter of judicious selection, routinely adjusted in order to optimize yield of the analyte compound/active fraction of plant material.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (US 4,018,755) in view of Bloom (US 5,902, 224) in view of Yokotsuka et al. (US 4,064,277). The rejection of claim 5 over Wang is evidenced by Soinneae, P. (1997).

The teachings of Wang and Bloom were discussed *supra*. These references did not specifically teach where the temperature of extraction was adjusted to the claimed range of 20 °C to approximately 50°C.

Yokotsuka et al. (US 4,064,277) taught that proteins were extracted from defatted soybeans at room temperature (see entire patent, especially Example 8, columns 8-9).

Again, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. While Wang did not specifically teach that the temperature of the extraction was 20 °C to approximately 50°C it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal temperature conditions as temperature is considered an art-recognized result-effective variable which would have been routinely determined and optimized. Although Wang did not specifically teach that the temperature of the extraction was 20 °C to approximately 50°C, because soybean proteins were known to be extracted at room temperature (approx. 18°C to 23 °C) one of ordinary skill in the art would have had a reasonable degree of success in carrying out the claimed method because the ordinary artisan would have recognized that the proteins of Wang could have been extracted at room temperature according to Yokotsuka et al.

The Supreme court has acknowledged that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable variation..103 likely bars its patentability...**if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...

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**...the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results** (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

[If]... there are [a] finite number of identified, predictable solutions, [a] person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

\*This reference is merely relied upon to state an inherent characteristic of soybean and is not used in the basis for rejection *per se*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

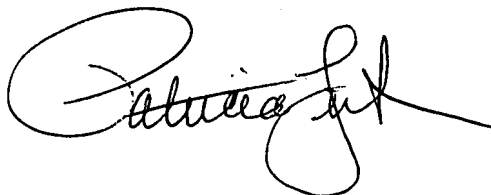
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith  
Primary Examiner  
Art Unit 1655

November 6, 2007

A handwritten signature in black ink, appearing to read 'Patricia Leith', with a large, stylized loop at the end.